

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 2 and 5** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 2** is indefinite because it is requiring for the form-retaining disc to be substantially oval and non-round at the same time.

**Claim 5** is indefinite because it is unclear as to what “a part” is referring to.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as being anticipated by Fay (US 6,231,617).

Regarding **claim 1**, Fay teaches a **liner** (Figure 1, item 10) **for connecting a prosthesis with the stump of an amputated lower leg, comprising a stocking** (Figure 1, item 16) **from a substantially flexible material** (column 4, lines 54-58) **for surrounding the stump with a first, open end** (Figure 3, item 14) **for receiving the stump therethrough, and a second, closed end** (Figure 1, item 12) **which is, on the outside, provided with a distal attachment plate** (Figure 3, item 13) (i.e. a **coupling means**) **for coupling to the prosthesis, wherein the stocking** (Figure 1, item 16) **is, on the inside, provided with a substantially form-retaining disc** (Figure 3, item 18c) **for supporting the end of the stump, and wherein the substantially form-retaining disc** (Figure 3, item 18c) **is substantially non-round** (column 5, lines 18-31) **in a view from the open end of the stocking.**

Regarding **claim 2**, Fay further teaches the substantially form-retaining disc to be substantially oval (Figure 2, item 18b) when viewed from the open end of the stocking.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. **Claims 3-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fay (US 6,231,617) in view of Klotz (US 5,529,575).

Regarding **claim 3**, Fay teaches all of the limitations set forth in claim 1, but fails to teach the form retaining disc to be substantially triangular in the view from the open end of the stocking.

However, Klotz teaches a cross-section of the bottom wall of prosthesis to be substantially triangular in shape (Figure 10). The bottom wall of the prosthesis, like the form retaining disc of the instant application, contacts the stump of the patient and is shaped to conform to the patient's stump (column 1, lines 65-67).

Fay and Klotz are concerned with the same field of endeavor, namely prostheses for lower leg amputees.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Fay by incorporating a triangular cross-section for the surface contacting the patient's stump, as taught by Klotz, in order to make a prosthesis that conforms to the patient's stump.

Regarding **claim 4**, Klotz further teaches the corners to be rounded.

Regarding **claim 5**, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the substantially triangular disc to be arranged for supporting the tibia with a part which is located near a corner of the triangle. Such a modification is well within the technical grasp of one ordinary

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skill in the art and creates predictable results of creating a more functional and comfortable prosthetic. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

Regarding **claim 6**, Fay teaches the disc to have a convex design (i.e. a substantially cup-shaped design) (column 5, lines 18-19).

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE WOZNICKI whose telephone number is (571)270-5603. The examiner can normally be reached on Monday through Thursday 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoa Huynh can be reached on (571)272-4888. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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